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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,089

09/10/2007

Kristina Allen

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

09/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,089	Applicant(s) ALLEN ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's response to species election of 5/5/2009 is acknowledged. Applicant elected Tween, superdex 200, Nacl, HEK293T and his₆Tag tag for examination purposes with traverse. In view of applicant's traversal arguments all species are hereby rejoined.

Claims 1-32 are under examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy (U.S. Patent No. 7,446,181, issued Nov. 4, 2008) in view of current large scale recombinant protein isolation and purification methods. McCarthy In columns 81-82 teaches a large scale method of hDkk3 (a mammalian Dkk protein) production involving harvesting culture media from 293Tcells transfected with hDkk3-3flag DNA, wherein said Dkk protein is secreted into the media, loading the media onto an affinity column, eluting the Dkk protein fraction (which displayed a molecular weight of 40-65 kDa under SDS-PAGE gel stained by coomassie) and dialyzing (purifying said protein) in phosphate buffer saline, thereby obtaining a concentrated hDKK3 solution. In column 54 McCarthy teaches that detergent (such as triton X-100, Tween, etc.) addition to Dkk

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protein solution may help keeping said proteins in solution. Mc Carthy also teaches about hDkk1-4, mDkk1, XDkk1 etc. See tables II-IV.

McCarthy does not teach utilizing specific EDTA or tween concentrations taught in claims 9-11, additional columns such as size exclusion chromatography, addition of protease inhibitors for mammalian Dkk protein purification, addition of His or c-myc tags to DNA encoding Dkk protein(s), or lyophilizing said protein after isolation.

Current large scale protein isolation and purification techniques teach the types and number of affinity columns , protease inhibitors (which protect proteins against protease attack), EDTA (to extract non desired metals and ions), the types of affinity tags (to aid purification) and detergent (to keep the protein soluble in solution) concentrations to be used and ways of storing said isolate proteins (in dry (lyophilized) form or in solution) for any desired protein.

At the time the invention was made, it would been obvious to one of ordinary skill in the art to start with the method of McCarthy and fine tune it in terms of salt, EDTA and detergent concentrations needed, the types of affinity columns and protease inhibitors and affinity tags to be used etc. and optionally lyophilizing said isolated proteins, according to current protein large scale isolation and purification techniques, depending on the type of Dkk protein to be purified, focusing on obtaining high yield and activity. Since all Dkk proteins specially hDkk1-4 are very similar in structure, it is reseanoably expected that the method of McCarthy in view of current large scale protein isolation and purification techniques may be easily applicable to each protein thereby resulting in purified proteins including hDkk1 of this invention, which would inherently

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have a molecular weight of 40kD (see claim 28) or average molecular mass of 36-46 kD (see claim 29) with a His or c-myc tag, rendering the invention obvious.

One of ordinary skill in the art is motivated in purifying the Dkk proteins (including hDkk 1-4) of McCarthy because said proteins are known to inhibit Wnt signaling, which may lead to cancer.

Finally, one of ordinary skill in the art has a reasonable expectation of success in conducting the methods of McCarthy in view of current large scale protein purification and isolation techniques and isolating the Dkk protein(s) because methods of isolating and purifying recombinant proteins are well established in the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656
